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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,757	06/06/2005	Zhi-Cheng Xiao	0380-P03638US0	5465

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EXAMINER

DUTT, ADITI

ART UNIT	PAPER NUMBER
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1649

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/537,757	Applicant(s) XIAO, ZHI-CHENG	
	Examiner Aditi Dutt	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 16-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-9 and 16-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-4, 7-9 and 16, drawn to a composition comprising Nogo and Caspr in combination with a carrier and a method of stimulating myelination of an axon by contacting a neuron or an oligodendroglial cell with the composition.

Group II, claim(s) 1-2 and 7-9 drawn to a composition comprising Nogo and Caspr mimetic in combination with a carrier.

Group III, claim(s) 1 and 5-9 drawn to a composition comprising a substance capable of promoting interaction between Nogo and Caspr in combination with a carrier.

Group IV, claim(s) 16, drawn to an in vitro method of stimulating myelination of an axon by contacting a neuron or an oligodendroglial cell with a composition comprising Nogo and Caspr mimetic.

Group V, claim(s) 16, drawn to an in vitro method of stimulating myelination of an axon by contacting a neuron or an oligodendroglial cell with a composition comprising a substance capable of promoting interaction between Nogo and Caspr.

Group VI, claim(s) 16-18, drawn to a method of treatment of a disease or injury to central nervous system (CNS) by administration of a pharmaceutical composition comprising Nogo and Caspr to a subject.

Group VII, claim(s) 16-18, drawn to a method of treatment of a disease or injury to central nervous system (CNS) by administration of a pharmaceutical composition comprising Nogo and Caspr mimetic to a subject.

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Group VIII, claim(s) 16-18, drawn to a method of treatment of a disease or injury to central nervous system (CNS) by administration of a pharmaceutical composition comprising a substance capable of promoting interaction between Nogo and Caspr to a subject.

Group IX, claim(s) 19-26, drawn to a method of screening for a candidate substance capable of modulating the interaction between Nogo and Caspr.

2. The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I recites the special technical feature of a composition comprising Nogo and Caspr and using the composition for stimulating myelination of an axon, which is not required by the other products or methods of Groups II-IX.

Group II recites the special technical feature of a composition comprising Nogo and Caspr mimetic, which is not required by the other products of Groups I and III.

Group III recites the special technical feature of a composition comprising a substance capable of promoting Nogo and Caspr interaction, which is not required by the other products of Groups I and II.

Group IV recites the special technical feature of stimulating myelination of an axon by contacting a neuron in vitro with the composition comprising Nogo and Caspr mimetic, which is not required by the other methods of Groups V-IX.

Group V recites the special technical feature of stimulating myelination of an axon by contacting a neuron in vitro with the composition comprising a substance capable of promoting Nogo and Caspr interaction, which is not required by the other methods of Groups IV and VI-IX.

Group VI recites the special technical feature of treating a CNS disease or injury by administration of a pharmaceutical composition comprising Nogo and Caspr to a subject, which is not required by the other methods of Group IV-V and VII-IX.

Group VII recites the special technical feature of treating a CNS disease or injury by administration of a pharmaceutical composition comprising Nogo and Caspr mimetic to a subject, which is not required by the other methods of Group IV-VI and VIII-IX.

Group VIII recites the special technical feature of treating a CNS disease or injury by administration of a pharmaceutical composition comprising a substance capable of

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promoting Nogo and Caspr interaction to a subject, which is not required by the other methods of Group IV-VII and IX.

Group IX recites the special technical feature of screening of a candidate substance capable of modulating the interaction between Nogo and Caspr, which is not required by the other methods of Group IV-VIII.

Species Election

A) CNS disorder or CNS injury

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- a) SCI (spinal cord injury)
- b) MS (multiple sclerosis)
- c) Epilepsy
- d) Stroke

The claims are deemed to correspond to the species listed above in the following manner:

Claim 18

The following claim(s) is generic: 17.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the above diseases of the CNS has a characteristically different etiology, treatment options and levels of success from one another and, therefore, will represent a patentably distinct invention and would require a separate search of the art that would be burdensome to the examiner. For example, the special technical feature of (d) is SCI. This special technical feature is not shared by the other species.

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4. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

5. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. In response to this Office Action/Election requirement, applicant must elect one from Groups I-IX and must additionally elect a species of CNS disease or injury for consideration.

7. Applicant is advised that in order for the reply to this requirement to complete it must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48 (b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be

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accompanied by a petition under 37 C.F.R. 1.48(b) and by the required under 37 C.F.R. 1.17(I).

Notice of Rejoinder

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

Amendments submitted after final rejection are governed by 37 CFR 1.116;

amendments submitted after allowance are governed by 37 CFR 1.312.

10. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See

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"Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Advisory Information

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aditi Dutt whose telephone number is 571-272-9037.

The examiner can normally be reached on M-F.

12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AD
25 September 2006

Bridget E. Bunner

**BRIDGET BUNNER
PATENT EXAMINER**